Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12508

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MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

CFSAN

Page ___ of ___

Form Approved OMB No 0910-0291 Expires 12/31/94
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 69026
12508

A. Patient information

1 Patient identifier [redacted] In confidence

2 Age at time of event: or Date of birth: [redacted]

3 Sex: [X] female [ ] male

4 Weight: 140 lbs or ___ kgs

B. Adverse event or product problem

1 [X] Adverse event and/or [ ] Product problem (e g , defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)
- [ ] death ___ (mo/day/yr)
- [ ] life-threatening
- [ ] hospitalization – initial or prolonged
- [ ] disability
- [ ] congenital anomaly
- [ ] required intervention to prevent permanent impairment/damage
- [ ] other ___

3 Date of event (mo/day/yr): 7-14-97

4 Date of this report (mo/day/yr): 8-1-97

5 Describe event or problem

Rapid Heart beat, Shortness of breath event happened while I was at rest, not during exercise or other strenuous activities

6 Relevant tests/laboratory data, including dates

7 Other relevant history, including preexisting medical conditions (e g , allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)

No Smoking pregnancy (heart murmur preexisting

AUG 29 P2:36

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known) (Bisenut, calculated as caffeine)

#1 SilverSage Thermogenics plus

#2 Mahuang (8% alkaloids = 14mg ephedrine)

2 Dose, frequency & route used
#1 3 daily/oral
#2 weight loss

3 Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 6-97/7-97
#2

4 Diagnosis for use (indication)
#1
#2

5 Event abated after use stopped or dose reduced
#1 [X] yes [ ] no [ ] doesn't apply
#2 [ ] yes [ ] no [ ] doesn't apply

6 Lot # (if known)
#1
#2

7 Exp. date (if known)
#1
#2

8 Event reappeared after reintroduction
#1 [ ] yes [ ] no [X] doesn't apply
#2 [ ] yes [ ] no [ ] doesn't apply

9 NDC # (for product problems only)
– –

10 Concomitant medical products and therapy dates (exclude treatment of event)

RECEIVED
AUG 29 1997

D. Suspect medical device

1. Brand name

2 Type of device

3 Manufacturer name & address

REC'D.
AUG 26 1997

4 Operator of device
- [X] health professional
- [ ] lay user/patient
- [ ] other: ___

5 Expiration date (mo/day/yr)

6
model # ___
catalog # ___
serial # MEDWATCH CTU
lot # ___
other # ___

7. If implanted, give date (mo/day/yr)

8 If explanted, give date (mo/day/yr)

9 Device available for evaluation? (Do not send to FDA)
[ ] yes [ ] no [ ] returned to manufacturer on ___ (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

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E. Reporter (see confidentiality section on back)

1 Name, address & phone #

[redacted]

2 Health professional? [X] yes [ ] no

3 Occupation: medical assistant

4 Also reported to
- [ ] manufacturer
- [ ] user facility
- [ ] distributor

If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. [X]

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

RECEIVED
CLINICAL RESEARCH
REVIEW/OSN

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.